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highlighted (e.g., fluorescent or color contrast) or in bold type, be in lines generally parallel to the base on which the package rests as it is designed to be displayed, and be in one of the following sizes, whichever is greater:

(1) At least one-quarter as large as the size of the most prominent printed matter on the PDP, or

(2) At least as large as the size of the “Drug Facts” title, as required in §201.66(d)(2). The new warnings information statement must remain on the PDP of the drug product for at least 1 year from the date the product is initially introduced into interstate commerce.

(c) *Requirements to supplement approved application.* Holders of approved applications for OTC drug products that contain internal analgesic/antipyretic active ingredients that are subject to the requirements of paragraph (a) of this section must submit supplements under §314.70(c) of this chapter to include the required information in the product’s labeling. Such labeling may be put into use without advance approval of FDA provided it includes at least the exact information included in paragraph (a) of this section.

[74 FR 19407, Apr. 29, 2009; 74 FR 31180, June 30, 2009, as amended at 74 FR 61514, Nov. 25, 2009]

EFFECTIVE DATE NOTE: At 74 FR 19407, Apr. 29, 2009, as corrected at 74 FR 31180, June 30, 2009, and amended at 74 FR 61514, Nov. 25, 2009, §201.326 was added, effective Apr. 29, 2010.

APPENDIX A TO PART 201—EXAMPLES OF GRAPHIC ENHANCEMENTS USED BY FDA

I. SECTION 201.66 STANDARD LABELING FORMAT

A. Overall

1. The “Drug Facts” labeling is set off in a box or similar enclosure by the use of a barline with all black type printed on a white, color contrasting background.

B. Typeface and size

1. “Drug Facts” is set in 14 point Helvetica Bold Italic, left justified.

2. “Drug Facts (continued)” is set in 8 point Helvetica Bold Italic for the words “Drug Facts” and 8 point Helvetica Regular for the word “(continued)” and is left justified.

3. The headings (e.g., “Directions”) are set in 8 point Helvetica Bold Italic, left justified.

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4. The subheadings (e.g., “Ask a doctor or pharmacist before use if you are”) are set in 6 point Helvetica Bold, left justified.

5. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.

6. The heading “Purpose” is right justified.

7. The bullet is a 5-point solid square.

8. Two em spacing separates bullets when more than one bullet is on the same line.

9. A table format is used for 3 or more dosage directions.

10. A graphic appears at the bottom of the first panel leading the reader to the next panel.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the “Drug Facts” box (or similar enclosure), providing separation between each of the headings.

2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the “Drug Facts” box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

3. A 0.5-point horizontal hairline follows the title, immediately preceding the heading, when a heading appears on a subsequent panel immediately after the “Drug Facts (continued)” title.

D. Box or Enclosure

1. All information is enclosed by a 2.5-point barline.

II. SECTION 201.66 MODIFIED LABELING FORMAT

A. Overall

1. The “Drug Facts” labeling is presented in all black type printed on a white color contrasting background.

B. Typeface and size

1. “Drug Facts” is set in 9 point Helvetica Bold Italic, left justified.

2. The headings (e.g., “Directions”) are set in 8 point Helvetica Bold Italic, left justified.

3. The subheadings (e.g., “Ask a doctor or pharmacist before use if you are”) are set in 6 point Helvetica Bold, left justified.

4. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.

5. The heading “Purpose” is right justified.

6. The bullet is a 5-point solid square.

7. Bulleted information may start on same line as headings (except for the “Warnings” heading) and subheadings, with 2 em spacing separating bullets, and need not be vertically aligned.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the “Drug Facts” box (or similar

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D. Box or Enclosure

2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the “Drug Facts” box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

III. EXAMPLES OF § 201.66 STANDARD LABELING AND MODIFIED LABELING FORMATS

Title: 14 pt. Helvetica Bold
Italic, left justified

Body text: 6 pt. Helvetica Regular with 6.5 pts. leading, left justified

Subheadings: 6 pt. Helvetica Bold, left justified

Bullet: 5 pt. Solid square

Headings: 8 pt. Helvetica Bold Italic, left justified

Drug Facts

| Active ingredient (in each tablet) | Purpose |
|------------------------------------|---------------|
| Chlorpheniramine maleate 2 mg..... | Antihistamine |

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

- glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

- you may get drowsy ■ avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

| | |
|---------------------------------------|---|
| adults and children 12 years and over | take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours |
| children 6 years to under 12 years | take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours |
| children under 6 years | ask a doctor |

8 pt. Helvetica Regular

Title:
9 pt. Helvetica Bold
Italic, left justified

Body text:
6 pt. Helvetica Regular with
6.5 pts. leading, left justified

Bullet: 5 pt.
Solid square

Subheadings:
6 pt. Helvetica Bold,
left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Drug Facts

| Active ingredients (in each tablet) | Purpose |
|-------------------------------------|---------|
| Aluminum hydroxide gel 200 mg..... | Antacid |
| Magnesium hydroxide 200 mg..... | Antacid |
| Simethicone 25 mg..... | Antigas |

Uses

- relieves symptoms referred to as gas
- relieves: ■ heartburn ■ acid indigestion ■ sour stomach
- upset stomach due to these symptoms

Warnings

Ask a doctor before use if you have kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last for more than 2 weeks

Keep out of reach of children.

Directions ■ chew 1 to 4 tablets 4 times daily

■ do not take more than 16 tablets in 24 hours or use the maximum dosage for more than 2 weeks

Inactive ingredients D&C red no. 30, D&C yellow no. 10, dextrose, FD&C blue no. 1, glycerin, magnesium stearate, mannitol, saccharin sodium, sorbitol, starch, sugar, talc

Right justified

2.5 point barline

0.5 point hairline

Bulleted information may start on same line as headings (except Warnings) and subheadings and need not be vertically aligned

Dark type on light background

Box barline omitted; color contrast used to highlight Drug Facts information